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PTO/SB/21 (09-04)
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/663,265
	Filing Date	September 16, 2003
	First Named Inventor	Edith Mathiowitz
	Art Unit	1633
	Examiner Name	Maria Gomez Leavitt
Total Number of Pages in This Submission	Attorney Docket Number	BU MAT 1993-04f DIV3CON2

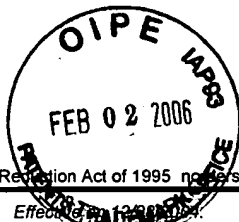
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Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Patrea L. Pabst		
Date	January 27, 2006	Reg. No.	31,284

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PTO/SB/17 (12-04)

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Effective 12/28/2004

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

Complete if Known

Application Number	10/663,265
Filing Date	September 16, 2003
First Named Inventor	Edith Mathiowitz
Examiner Name	Maria Gomez Leavitt
Art Unit	1633
Attorney Docket No.	BU MAT1993-04fDIV3CON2

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☒ Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
16	- 20 or HP = 0	x	=			

HP = highest number of total claims paid for, if greater than 20

<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
2	- 3 or HP = 0	x	=

HP = highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- 100 =	/ 50 =	(round up to a whole number) x	=	

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: _____

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	31,284	Telephone	(404) 879-2151
Name (Print/Type)	Patrea L. Pabst	Date	January 17, 2006		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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BU MAT1993-04fDIV3CON2 / 077042-00035



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Edith Mathiowitz, Yong Shik Jong, and Kim Boekelheide

Serial No.: 10/663,265

Art Unit: 1633

Filed: September 16, 2003

Examiner: Maria Gomez Leavitt

For: *POLYMERIC GENE DELIVERY SYSTEM*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including (6) pages of Form PTO-1449 and copies of two (2) documents cited therein. **The Attorney Docket Number for this application is currently incorrect.**

Please change the Attorney Docket Number to BU MAT1993-04fDIV3CON2.

Most of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/815,807, filed March 23, 2001, now U.S Patent No. 6,620, 617 to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies of the newly cited documents, which are identified with an asterisk (*), are enclosed.

This Information Disclosure Statement is being filed under 37 C.F.R §1.97 (c) before the mailing date of any of a final action under §1.311. The Commissioner is hereby authorized to charge a fee of \$180.00 to Deposit Account No. 50-3129, representing the fee required under 37

C.F.R. §1.17(p). It is believed that no additional fees are required with this submission.

However, should a fee be required, the Commissioner is hereby authorized to charge any fees to

Deposit Account No. 50-1329.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,272,398	06-09-1981	Jaffe	427/213.31
4,775,624	10-04-1988	Bang, et al.	435/226
4,861,627	08-29-1989	Mathiowitz, et al.	427/213.31
4,863,735	09-05-1989	Kohn, et al.	424/422
4,897,355	01-30-1990	Eppstein, et al.	424/450
4,898,734	02-06-1990	Mathiowitz, et al.	424/426
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5,271,961	12-21-1992	Mathiowitx, et al.	427/213.31
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5,792,751	08-11-1998	Ledley, et al.	514/44
5,820,883	10-13-1998	Tice, et al.	424/501
5,880,103	03-09-1999	Urban, et al.	514/44

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 248 531	12-09-1987	Southern Research Institute	EP
0 330 180	08-30-1989	Biomaterials Universe, Inc.	EP
0 302 582	02-08-1989	Southern Research Institute	EP
5 79347	01-19-1994	Ferring Arzneimittel, GMBH	EP
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*WO 94/23699	10-27-1994	Medisorb Technologies International L	PCT
WO 94/23738	10-27-1994	Medisorb Technologies	PCT

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ACSADI, et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs", *Nature*, 352(6338):815-8 (1991).

BENITA, et al., "Characterization of drug-loaded poly(d,l-lactide) microspheres", *J Pharm Sci.*, 73(12):1721-4 (1984).

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CLARK, "Overview and general considerations of wound repair", in The Molecular and Cellular Biology of Wound Repair eds. R Clark and P Henson, pp 3-33 1988.

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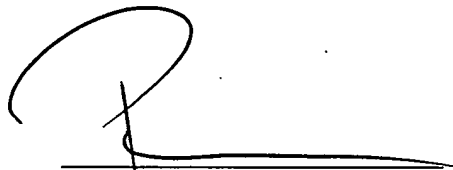
WOLFF, et al. "Direct gene transfer into mouse muscle in vivo" *Science*, 247(4949 Pt 1):1465-8 (1990).

YANG, "Gene transfer into mammalian somatic cells *in vivo*", *Critical Reviews in Biotechnology*, 12(4):335-356 (1992).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Patrea L. Pabst', written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: January 27, 2006

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		Complete if Known	
		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
Sheet 1 of 6	Attorney Docket Number	BU MAT1993-04fDIV3CON2	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,272,398		Jaffe	06-09-1981	
		4,775,624		Bang, et al.	10-04-1988	
		4,861,627		Mathiowitz, et al.	08-29-1989	
		4,863,735		Kohn, et al.	09-05-1989	
		4,897,355		Eppstein, et al.	01-30-1990	
		4,898,734		Mathiowitz, et al.	02-06-1990	
		5,100,669		Hyon, et al.	03-31-1992	
		5,100,792		Sanford, et al.	03-31-1992	
		5,171,217		March, et al.	12-15-1992	
		5,271,961		Mathiowitx, et al.	12-21-1992	
		5,366,881		Singh, et al.	11-22-1994	
		5,639,473		Grinstaff, et al.	06-17-1997	
		5,643,578		Robinson, et al.	07-01-1997	
		5,674,192		Sahatjian, et al.	10-07-1997	
		5,763,416		Banadio, et al.	06-09-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0 248 531		Southern Research Institute	12-09-1987		
		EP	0 330 180		Biomaterials Universe, Inc.	08-30-1989		
		EP	0 302 582		Southern Research Institute	02-08-1989		
		EP	5 79347		Ferring Arzneimittel, GMBH	01-19-1994		
		PCT	WO 93/0885		Massachusetts Institute of Technology	05-123-1993		

Examiner's Signature	Date Considered
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				Application Number	10/663,265
				Filing Date	September 16, 2003
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				Examiner Name	Maria Gomez Leavitt
Sheet	2	of	6	Attorney Docket Number	BU MAT1993-04fDIV3CON2

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		Number	Kind Code ² (if known)			
		5,783,567		Hedley, et al.	07-21-1998	
		5,792,751		Ledley, et al.	08-11-1998	
		5,820,883		Tice, et al.	10-13-1998	
		5,880,103		Urban, et al.	03-09-1999	
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FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 93/21906		Brown University Research Foundation	11-11-1993		
		PCT	WO 93/25221		Alkermes Controlled Therapeutics	12-23-1993		
		PCT	WO 94/23699		Medisorb Technologies International LP	10-27-1994		
		PCT	WO 94/23738		Medisorb Technologies International LP	10-27-1994		

Examiner's Signature		Date Considered	
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¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

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				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
Sheet	3	of	6	Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ACSADI, et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs", <i>Nature</i> , 352(6338):815-8 (1991).	
		BENITA, et al., "Characterization of drug-loaded poly(D,L-lactide) microspheres", <i>J Pharm Sci.</i> , 73(12):1721-4 (1984).	
		BLAU, "Muscular dystrophy. Muscling in on gene therapy", <i>Nature</i> , 364(6439):673-5 (1993).	
		CHANGBEN and SHOUYUAN, "Use of human erythrocyte ghosts for transfer of 125I-BSA and 125I-DNA into animal cells through cell fusion", <i>Scientia Sinica</i> , XXV(8):860-865 (1982).	
		COGHLAN, et al., "Gene dream fades away" <i>New Sci.</i> , 148(2005):14-5 (1995).	
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				Filing Date	September 16, 2003
				First Named Inventor	Edith Mathiowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
Sheet	4	of	6	Attorney Docket Number	BU MAT1993-04fDIV3CON2

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		EISENBRAUN, et al., "Examination of parameters affecting the elicitation of humoral immune responses by particle bombardment-mediated genetic immunization", <i>DNA Cell Biol.</i> , 12(9):791-7 (1993).	
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		MATHIOWITZ, et al., "Polyanhydride microspheres II. Microencapsulation by solvent removal", <i>J. Appl Polymer Sci.</i> , 35:755- (1988).	
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		ULMER, et al. "Heterologous protection against influenza by injection of DNA encoding a viral protein", <i>Science</i> , 259(5102):1745-9 (1993).	
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